DEC 1 3 2000

K00 3144

510(k) Summary of Safety and Effectiveness

Device Name	Model 205GE-64: Pathway MRI™ Carotid Array Coil
Applicability	Compatible with GE Signa 1.5T MRI systems with Phased Array option
Reason for 510(k)	New device
Classification Name	Magnetic Resonance Diagnostic Device
Device Classification Panel	Radiology
Device Classification Number	892.1000
Product Code	90MOS
Common Name	Magnetic Resonance Specialty
Proprietary Name	Model 205GE-64: Pathway MRI™ Carotid Array Coil
Establishment Registration Number	2183683
Address of MFG Facility	Device manufactured by: IGC-Medical Advances Inc. 10437 Innovation Drive Milwaukee: WI 53226 U.S.A. Contact: Thomas E. Tynes, Director of Operations 414.258.3808 Ext. 407

Points of Contact	IGC-Medical Advances Inc. Thomas E. Tynes Director of Operations 414.258.3808 Ext. 407 Pathway MRI™, a Pathway Medical Technologies Company Louise C. Myers Vice President, Regulatory Affairs 425.497.0372
Classification	Class II
Intended Uses	
Diagnostic Uses	2D, 3D imaging, proton density, T1 and T2 weighted imaging. 2D, 3D time of flight, phase contrast imaging.
Anatomic Regions	Head: Orbits, inner ear structures, Temporomandibular joint Upper Neck: Targeted MRA, bifurcation of the carotid artery Upper Extremities: Small joints, bones, and peripheral nerves of the elbow, hand, and wrist Lower Extremities: Small joints and peripheral nerves of the ankle, foot, toes, and Achilles Tendon Pediatric applications
Standards	
Performance Standards	None Established under Section 514
Voluntary Safety Standards	UL 2601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety UL 94 Tests for Flammability of Plastic Materials IEC 601-1 General Safety Requirements for Medical Electrical Equipment CPAI-84 Specification for Flame Resistant Material Used in Camping Tentage

Overview

The Radiology Devices Panel considered potential concerns regarding the safe and effective operation of Magnetic Resonance Diagnostic Devices when they recommended reclassification to Class II on July 27, 1987. After reclassification, the FDA's Center for Devices and Radiological Health (CDRH) released a draft guidance document for the content and review of Magnetic Resonance Diagnostic Device premarket notification submissions that offered clarification of these concerns. Due to considerable technological advances in MRDDs, CDRH issued an updated guidance document on November 14, 1998. The following is a summary of the information contained within this premarket notification that addresses these concerns:

The GE 1.5T Signa MRI system operated with the Pathway MRI™ Carotid Array Coil is substantially equivalent to the same system operated with the legally marketed predicate devices listed in section 4.0, within the Class II definition of Magnetic Resonance Diagnostic Device with respect to the safety parameter action levels:

Safety Parameters

Maximum Static Magnetic Field:	No change
Rate of Magnetic Field Strength Change:	No change
RF Power Deposition:	No change
Acoustic Noise Levels:	No change
Biocompatibility:	No change

Imaging Performance Parameters

Specification Volume:	No change
Signal-to-Noise Ratio:	No change
Image Uniformity:	No change
Geometric Distortion:	No change
Slice Thickness and Gap:	No change
High Contrast Spatial Resolution:	No change

General Safety and Effectiveness Concerns

The device contains instructions for use. It includes indications for use, precautions, cautions, contraindications, warnings and quality assurance testing. This information assures safe and effective use of the device.

Substantial Equivalence Summary

The GE 1.5T Signa MRI system operated with the Pathway MRI™ Carotid Array Coil addressed in this PMN, has the same intended use and technological characteristics as the same system operated with the identified legally marketed predicate devices. The use of these coils does not affect the GE Signa system safety parameter specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2000

Mr. Thomas E. Tynes
Director of Operations
IGC-Medical Advances, Inc.
10437 Innovation Drive
MILWAUKEE, WI 53226

Re: K003144
Model 205 Series: Pathway MRI™
Carotid Array Coil
Dated: October 9, 2000
Received: October 10, 2000
Regulatory Class: II
21 CFR §892.1000/Procode: 90 MOS

Dear Mr. Tynes:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K03 3144

Device Name: Model 205GE-64: Medical Advances Pathway MRI™ Carotid Array Coil

Indications for Use:
Magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA) of the Head: Orbits, inner ear structures, Temporomandibular joint. Upper Neck: Targeted MRA, bifurcation of the carotid artery. Upper Extremities: Small joints, bones, and peripheral nerves of the elbow, hand, and wrist. Lower Extremities: Small joints and peripheral nerves of the ankle, foot, toes, and Achilles Tendon. Pediatric applications.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003144